UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| In re Mylan N.V. Securities Litigation | Case No. 1:16-CV-07926 (JPO)<br><br>**MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT** |

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## TABLE OF ABBREVIATIONS¶¶

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| **1990 Act** | Omnibus Budget Reconciliation Act of 1990 |
| **2012 Settlement Agreement** | April 26, 2012 agreement between Mylan, Meridian Medical Technologies Inc., King Pharmaceuticals and Teva Pharmaceuticals |
| **2016 10-K** | Mylan Inc. or Mylan N.V.'s Annual Report on Form 10-K to the SEC filed February 16, 2016 |
| **2016 Regulations** | 42 C.F.R. § 447.500 *et seq.* (2016) |
| **2016 8-K** | Mylan N.V.'s 8-K Current Report on Form 8-K to the SEC filed October 7, 2016 |
| **AC** | Amended Class Action Complaint for Violation of Securities Laws (March 20, 2017) (Dkt. 39) |
| **Amended Complaint** | Amended Class Action Complaint for Violation of Securities Laws (March 20, 2017) (Dkt. 39) |
| **AMP** | Average Manufacturer's Price |
| **ANDA** | Abbreviated New Drug Application |
| **Class Period** | February 21, 2012 to January 29, 2017 |
| **CMS** | Centers for Medicare and Medicaid Services |
| **Company** | Mylan N.V. and/or Mylan Inc. |
| **CW** | Confidential Witness |
| **Defendants** | Mylan N.V., Mylan Inc., Heather Bresch, Robert J. Coury, Paul B. Campbell, Kenneth S. Parks, and John D. Sheehan |
| **Dey** | Dey Inc. or Dey L.P. |
| **DOJ** | U.S. Department of Justice |
| **doxycycline** | doxycycline hyclate delayed release |
| **DTC** | Depository Trust Company |
| **EpiPen** | EpiPen Auto-Injector® and EpiPen Jr. Auto-Injector® |
| **FDA** | U.S. Food and Drug Administration |
| **Heritage** | Heritage Pharmaceuticals Inc. |
| **HHS** | Department of Health and Human Services |
| **HHS IG** | Department of Health and Human Services Inspector General |
| **I drug** | innovator multiple source drug |
| **Individual Defendants** | Heather Bresch, Robert J. Coury, Paul B. Campbell, Kenneth S. Parks and John D. Sheehan |
| **Israel Securities Law** | Israel Securities Law of 1968 |
| **Israeli Investor Group** | Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd. |
| **MDRP** | Medicaid Drug Rebate Program |
| **Mylan** | Mylan N.V. and/or Mylan Inc. |
| **N drug** | noninnovator multiple source drug |
| **NDA** | New Drug Application |

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| **Plaintiffs** | Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd. and Dan Kleinerman |
| **Price-Fixed Drugs** | albuterol sulfate, benazepril, clomipramine, divalproex and propranolol |
| **SOX** | Sarbanes-Oxley Act of 2002 |
| **SEC** | United States Securities and Exchange Commission |
| **Section 10(b)** | Securities Exchange Act, 15 U.S.C. § 78j(b) |
| **Section 20(a)** | Securities Exchange Act, 15 U.S.C. § 78t(a) |
| **S drug** | single source drug |
| **TASE** | Tel Aviv Stock Exchange |
| **TASE Investor Class** | All purchasers of Mylan N.V. common stock made on the Tel Aviv Stock Exchange during the Class Period |
| **Teva** | Teva Pharmaceuticals |

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**Cases**

**Statutes**



**Other Authorities**

## I. PRELIMINARY STATEMENT

As is clear from even a cursory review of the facts, Mylan engaged in rampant corrupt activity during the Class Period. Plaintiffs have brought this Action because, during the Class Period, Defendants misled investors about a course of conduct intended to cheat Medicaid (the U.S. low-income healthcare program) out of its rightful rebates for EpiPen purchases, about anticompetitive agreements it extracted from competitors and grade schools that allowed it to inflate the price of this lifesaving drug astronomically, beyond the reach of many consumers, and about a scheme to inflate the prices of critical generic drugs by 1000% or more by conspiring with other generic drug companies to fix the prices of these drugs.

This massive and wide-reaching wrongdoing certainly violated federal regulations and antitrust laws, but just as importantly if not more so, the wrongdoing amounted to egregious violations of the federal securities laws—Mylan made numerous statements throughout the Class Period covering all of the areas of activity in which it committed wrongdoing, yet failed to disclose the wrongdoing, as Defendants were required to do in order to make these statements to the investing public not misleading. By misleading the investing public, Mylan caused *billions* of dollars of losses to Plaintiffs, losses that cannot be recovered through any other causes of action. Securities laws are not redundant.

Unsurprisingly, Defendants' attempt to dismiss this case resoundingly fails. Defendants' motion fails even to purport to provide a reason to dismiss at least two of Plaintiffs' categories of misstatements, which now will move forward regardless of the motion.[1] Plaintiffs' remaining categories all emerge from this motion similarly unscathed—Defendants' arguments to dismiss them ignore critical, well-pleaded facts, fundamental, controlling law, or both.

[1] *See infra*, Part III(A)(1)(a), (B)(1), and (C) note 19. "[A]s a general rule, courts will not consider arguments raised for the first time in a reply brief." *Okor v. Borough of Manhattan Cmty. Coll.*, No. 14-CV-1593 (JPO), 2015 U.S. Dist. LEXIS 77859, at *12-13 n.6 (S.D.N.Y. June 16, 2015) (Oetken, J.)

## II. FACTUAL BACKGROUND

The facts as pleaded constitute multiple clear violations of federal securities laws.

### A. Mylan Knowingly Misclassified the EpiPen for the Purposes of the MDRP

The EpiPen® is a brand-name epinephrine auto-injector for the emergency treatment of severe allergic reactions (AC ¶ 26), and it is Mylan's most important product: sales of the EpiPen through Medicaid accounted for between 28% and 95% of Mylan's operating profits during the Class Period. (AC ¶¶ 33-39.)

The MDRP is a government program associated with Medicaid under which a drug company may receive state Medicaid coverage for the manufacturer's drugs if the manufacturer rebates a portion of its sales to Medicaid. (AC ¶¶ 41-42.) Under the MDRP, manufacturers are responsible for classifying their drugs as brand-name ("S" or "I") drugs or as generic ("N") drugs, and for rebating Medicaid's purchases of brand-name drugs at a rate of 23.1%, and generic drugs at a rate of 13%. (AC ¶¶ 43-44, 53.)

Classification for the purposes of the rebate is simple. (AC ¶¶ 59-63.) As Mylan itself repeatedly explained in no uncertain terms in its 10-K filings throughout the Class Period:

> The required rebate [under the MDRP] is currently 13% of the [AMP] for sales of [] products marketed under ANDAs . . . . Sales of [] products marketed under NDAs require manufacturers to rebate . . . 23% . . . .

(AC ¶ 64.) That is, under the MDRP, all drugs that are approved under NDAs must be classified as S or I drugs (and be subject to a 23% rebate), whereas all drugs that are approved under ANDAs must be classified as N drugs (and be subject to a 13% rebate). (AC ¶¶ 44, 53.) On at least two occasions since 2007, CMS issued clear guidance that this was the simple rule, and in both instances, CMS's statement of the rule constituted exactly one paragraph. (AC ¶¶ 48-49.)

Mylan has consistently misclassified the EpiPen as a generic N drug. (AC ¶¶ 57-65.) The EpiPen is marketed under an NDA, and under the simple rule for classification of drugs

under the MDRP that Mylan itself repeatedly stated in its SEC filings, Mylan was required to classify the EpiPen as an S or I drug and to give Medicaid the greater rebate applicable to brand-name drugs of approximately 23% of AMP. (AC ¶¶ 55, 59-64.)

Mylan clearly knew the EpiPen was misclassified. (AC ¶¶ 57-75.) *CMS itself*, the agency responsible in the first instance for interpreting and implementing the 1990 Act, *expressly told Mylan* prior to the start of the Class Period that its classification of the EpiPen as a generic N drug was incorrect. (AC ¶ 65.) On March 16, 2009, the HHS IG provided CMS with a list of eight drugs, including the EpiPen, that it had determined to be misclassified. (*Id.*) Subsequently, CMS notified Mylan about the misclassification: as CMS stated to a member of Congress, "CMS has, on multiple occasions . . . . expressly told Mylan that [the EpiPen] is incorrectly classified." (*Id.*) Senator Grassley recently confirmed that "CMS provided records to the [Senate Judiciary] Committee that show CMS told Mylan on several occasions that the EpiPen was misclassified, yet Mylan failed to correct the classification," and that Mylan had "overcharged the taxpayers *for years* with the knowledge EpiPen was misclassified."[2]

Furthermore, in November 2014, Mylan received a subpoena from the DOJ as part of the DOJ's investigation into "whether EpiPen Auto-Injector was properly classified with [CMS]." (AC ¶ 72.) Accordingly, by November 2014 at the very latest, even the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan's classification of the EpiPen for the purposes of the MDRP was likely incorrect. (*Id.*) On October 7, 2016, Mylan announced that it had agreed to the terms of a $465 million settlement with the DOJ over its misclassification of the EpiPen, though the settlement was never finalized. (AC ¶¶ 85-88.) Senator Warren called the announced settlement "shamefully weak"

[2] Charles Grassley, *Grassley: Latest Estimate is Taxpayers Overpaid $1.27 Billion for EpiPen* (May 31, 2017) *available at* https://www.grassley.senate.gov/news/news-releases/grassley-latest-estimate-taxpayers-overpaid-127-billion-epipen (emphasis added).

and "shockingly soft." (AC ¶ 87.) Analysts estimate that Mylan overcharged Medicaid for its EpiPen purchases by between $707 million and $1.27 billion. (AC ¶ 311; *see supra*, note 2.)

### B. Mylan Entered Anticompetitive Agreements To Allow It To Inflate the Price of the EpiPen

During the Class Period, Mylan entered into anticompetitive exclusive dealing agreements with schools that required the schools to agree not to purchase products competitive with the EpiPen in order to purchase the EpiPen at an affordable price. (AC ¶¶ 101-03.) Mylan also participated in an anticompetitive pay-for-delay agreement with Teva under which Mylan paid Teva a so-called "reverse payment"—a payment solely in exchange for Teva's agreeing to delay the introduction of its generic substitute for the EpiPen (AC ¶¶ 93-100.) Mylan made numerous statements during the Class Period that were false or misleading in light of these agreements, which Defendants clearly could not have entered into unknowingly.

### C. Mylan Engaged in Market Allocation and Price Fixing of Generic Drugs

During the Class Period, Mylan participated in a third massive fraud on investors—Mylan misled investors about a wide-ranging scheme to allocate the market between itself and competitors for at least one generic drug, doxycycline, in order to maintain its price at a supracompetitive level, and about a scheme to fix the prices of at least five other generic drugs by agreeing with competitors to raise the prices drastically and simultaneously. (AC ¶¶ 104-200.) The top executives at Mylan, including the Individual Defendants, knew of and participated in these conspiracies. (*See, e.g.*, AC ¶¶ 109-11.) Indeed, a confidential witness has confirmed that the Individual Defendants knew of and approved all material pricing decisions at Mylan. (*Id.*)

#### 1. Market Allocation of Doxycycline

In mid-2013, Heritage executives began to reach out to Mylan executives in an effort to divide the market for doxycycline in order to refrain from competing with each other on prices.

(AC ¶¶ 114-15.) On May 8, 2013, Heritage's President and CEO, Jeffrey Glazer spoke by telephone to an executive at Mylan to agree to allocate the market for doxycycline. (AC ¶ 116.) Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business from that wholesaler. (AC ¶ 118.) On August 29, 2014, Malek emailed Mylan that their agreement was still in effect. (AC ¶ 126.)

**2. Price Fixing Conspiracy**

Beginning in or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained price fixing agreements with the other major participants in the markets for the Fixed-Price Drugs. (AC ¶¶ 127-200.) For years prior to 2013, prices for the Fixed-Price Drugs had remained stable. (AC ¶¶ 130, 136, 142, 148, 154.) Immediately or soon after Defendants entered these agreements, Mylan and all other industry participants increased the prices of the Fixed-Price Drugs synchronously and astronomically, in each case by hundreds or thousands of percentage points. (*Id.*) These price increases followed industry meetings attended by Mylan senior executives in February and June 2013. (*Id.*) Mylan and its co-conspirators had numerous opportunities to meet to plan their conspiracy, at industry meetings, trade shows and private "industry dinners" among high-level executives. (AC ¶¶ 175-79.)

Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by Congress and federal and state antitrust regulators. (AC ¶¶ 188-200.) On December 14, 2016, the attorneys general of twenty states (the "States") filed a joint complaint against Mylan that was the product of a years-long investigation, and many of the allegations in the Amended Complaint are based in whole or in part on that complaint. (AC ¶¶ 14, 113, 127-200.) On January 9, 2017, Jeffrey Glazer and Jason Malek, the former CEO and President of Heritage, pleaded guilty to felony charges of conspiring with Mylan to fix prices, rig bids, and allocate customers for doxycycline. (AC ¶¶ 199-200.)

## III. ARGUMENT: PLAINTIFFS HAVE PROPERLY PLEADED VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT

### A. Plaintiffs Have Adequately Alleged Numerous Misleading and Material Statements and Omissions

The first element of a Section 10(b) claim requires a qualifying "misrepresentation or omission," which is any one that "viewed as a whole, would have misled a reasonable investor." *Berger v. Apple REIT Ten, Inc.*, 563 F. App'x 81, 83 (2d Cir. 2014). A misrepresentation is "material" if a reasonable investor likely would view it as "significantly alter[ing] the 'total mix' of information made available." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011).

Moreover, while it is trivially true that "the securities laws do not impose a general duty to disclose . . . uncharged criminal conduct" (Defs.' Mem. 12), nevertheless "[i]t is well-established precedent in this Circuit that once a company speaks on an issue or topic, there is a duty to tell the whole truth, even when there is no existing independent duty to disclose information" on the issue or topic. *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016); *see Meyer v. JinkoSolar Holdings Co.*, 761 F.3d 245, 251 (2d Cir. 2014).[3]

Defendants do not dispute, as they cannot, that the alleged misstatements and omissions were all material—the misstatements and omissions at issue concealed over a billion dollars of overcharges to Medicaid and egregious antitrust violations. Moreover, as explained below, Plaintiffs detail in the Amended Complaint numerous statements and omissions made by Defendants throughout the years-long Class Period that clearly were misleading. (AC ¶¶ 201-97). With respect to Defendants' omissions, Defendants spoke on each of the topics and issues about which they misled the public, as detailed in the Amended Complaint (AC ¶¶ 201-97), and so were under a duty to tell "the whole truth" relating to them. *In re Vivendi*, 838 F.3d at 258.

[3] *See also In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006) ("Though courts have held that the securities laws do not impose a duty to disclose uncharged criminal conduct, corporations are obligated to disclose facts necessary to ensure that their statements are not misleading. This duty applies to the disclosure of criminal conduct to the same extent it applies to the disclosure of any other material information.")

### 1. Mylan Misled Investors Regarding Its Misclassification of the EpiPen

Defendants made numerous material misrepresentations and omissions during the Class Period relating to its misclassification of the EpiPen for the purposes of the MDRP. (AC ¶¶ 201-224; 227-243; 246-261; 264; 266-273; 276-283; 285-295). The bulk of these misleading statements may be grouped into four categories based on the reason each was misleading: statements that were misleading because (1) Mylan failed to disclose that the EpiPen was misclassified ("EpiPen Misclassification Omissions");[4] (2) Mylan rebated Medicaid only 13% of AMP for EpiPen while Mylan implied that it was rebating Medicaid approximately 23% ("13% Rebate Omissions") (*e.g.*, AC ¶ 204); (3) Mylan failed to disclose that CMS had determined that the EpiPen was misclassified, and so had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken" ("CMS Determination Omissions") (*e.g.*, AC ¶ 206(5)); (4) Mylan was under investigation by the DOJ relating to its misclassification of EpiPen ("DOJ Investigation Omissions") (*e.g.*, AC ¶ 265(6)).

#### a. Defendants' CMS Determination Omissions and DOJ Investigation Omissions Were Misleading

Defendants rightly pass on any attempt to argue that the CMS Determination Omissions and DOJ Investigation Omissions were not material misrepresentations made by Defendants.

[4] *E.g.*, AC ¶¶ 202(1)-(2); 206(1), 206(3). Among the misstatements in this category are certain revenue and net income statements that were misleading because Mylan failed to disclose that its revenue and net income were inflated by the EpiPen misclassification. Contrary to Defendants' argument (Defs.' Mem. 13 n.10), statements of revenue that include revenue derived from fraud are misleading if they fail to disclose the fraud. *See, e.g.*, *In re Van Der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 407 (S.D.N.Y. 2005); *In re Marsh*, 501 F. Supp. 2d at 470; *In re LaBranche Sec. Litig.*, 405 F. Supp. 2d 333, 364-65 (S.D.N.Y. 2005). Moreover, contrary to Defendants' contention (Defs.' Mem. 8 n.7), statements that a company faces risk of a contingency that in fact has already occurred are misleading. *See, e.g.*, *In re Van Der Moolen*, 405 F. Supp. 2d at 400 ("to warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit"); *In re Facebook, Inc.*, 986 F. Supp. 2d 487, 518 (S.D.N.Y. 2013) (construing "present certainty as a future possibility" is actionable); *In re BioScrip, Inc.*, No. 13-CV-6922 (AJN), 2015 U.S. Dist. LEXIS 73484, at *17 (S.D.N.Y. June 5, 2015) (same); *see also Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004) ("Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired."); *In re iDreamSky Tech. Ltd. Sec. Litig.*, No. 15-CV-2514 (JPO), 2017 U.S. Dist. LEXIS 24786, at *9 (S.D.N.Y. Feb. 22, 2017) (Oetken, J.).

This Court previously has held that similar omissions of material government communications and commencement of an investigation under circumstances just like those present here are misleading and constitute legitimate bases for a Section 10(b) claim. *See Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 585 (S.D.N.Y. 2016).

**b. Defendants' EpiPen Misclassification Omissions Misstatements Were Misleading**

As for Mylan's EpiPen Misclassification Omissions, these statements were misleading because Mylan misclassified the EpiPen prior to and throughout the Class Period. At least two federal agencies, including HHS and CMS, the latter of which is responsible for administering the MDRP, have determined that the EpiPen is misclassified.[5] (*See* SOF; AC ¶ 65.)

The determination by these agencies that Mylan misclassified the EpiPen is clearly correct. As explained in the Amended Complaint and SOF, the EpiPen was marketed under an NDA, so under the simple rule for classification of drugs for the purposes of the MDRP, the EpiPen is to be classified as an S or I drug, both equally subject to the higher rebate amount under the MDRP.[6] (AC ¶¶ 40-53, 60.)

At no point in their opposition do Defendants claim that Mylan correctly classified the EpiPen, and so at no point do they directly dispute that the EpiPen Misclassification Omissions were misleading.[7] Instead, Defendants conflate the falsity and scienter requirements of

[5] The DOJ likewise appears to believe that the EpiPen was misclassified, as it issued subpoenas to Mylan on this topic in November 2014 and reached a tentative $465 million settlement agreement with Mylan concerning this misclassification. (AC ¶¶ 72, 85-88.)

[6] As explained in the Amended Complaint, the only exception to this rule is "narrow" and was stated in the 2016 Regulations; for the purposes of the classification of the EpiPen, all that is relevant about the narrow exception is that it never applies to drugs, like the EpiPen, "that received patent protection." (AC ¶ 51.)

[7] As for Mylan's 13% Rebate Omissions, Mylan's repeated and unequivocal statement of its understanding of the MDRP rules in its Annual Reports, that "[s]ales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate . . . 23% . . . of the [AMP]" (emphasis added), were patently misleading because Mylan rebated Medicaid only 13% of the AMP for sales of its most important product, the EpiPen, even though the EpiPen was marketed under an NDA. (AC ¶¶ 13, 58.) Defendants argue that Mylan's disclosure in other sections of its Annual Report, to the effect that classifications under the MDRP were subject to risk of error, somehow made its

Section 10(b) and argue that they could not *knowingly* have misclassified the EpiPen, arguments that Plaintiffs address below in the discussion of scienter. (*See infra*, Part III(B).)

**2. Mylan Misled Investors About Its Anticompetitive Agreements Relating to the EpiPen**

Mylan repeatedly misled investors during the Class Period by making statements regarding the means Mylan used to compete while omitting to disclose, among other things, that Mylan competed through anticompetitive exclusive dealing agreements with schools governing their purchases of the EpiPen, and through a pay-for-delay agreement with Teva designed to delay the entry of a generic competitor to the EpiPen. (*See, e.g.*, AC ¶¶ 244-45.)

Defendants argue that Plaintiffs failed adequately to plead that Mylan's exclusive dealing agreements or pay-for-delay agreement amounted to an antitrust violation. (Defs.' Mem. 8-9.) However, Section 10(b) requires only that Plaintiffs allege a misleading statement; a Plaintiff need adequately allege an antitrust violation in connection with a Section 10(b) claim only if the alleged misleading statements are false *solely* because the Defendant *committed an antitrust violation*. *See In re AXIS Capital Holdings Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 585 (S.D.N.Y. 2006) (requiring adequate antitrust allegations because claims were "entirely dependent" on antitrust violation); *Menaldi*, 164 F. Supp. 3d at 578 (same). Here, Mylan's failure to list exclusive-dealing and pay-for-delay agreements as among the means by which it competed misled investors into believing that Mylan did not employ such agreements, when in fact it did.

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own stated interpretation of the MDRP rules not misleading, even though Mylan secretly was not applying its own interpretation of the MDRP rules to the classification of its most important product. (Defs.' Mem. at 3 n.7.)

Defendants are wrong. A reasonable investor would view Mylan's statement of the MDRP classification rules as a statement of how Mylan interpreted those rules for the purpose of classifying its products, and would understand Mylan's disclosure that classifications under the MDRP are subject to risk of error to be a statement that Mylan's classifications according to its stated interpretation of the MDRP rules were subject to risk of error. Accordingly, a reasonable investor would understand Mylan's Annual Report, read as a whole, to indicate that Mylan rebated all drugs marketed under an NDA (including the EpiPen) at 23% of the AMP, but that Mylan's paying this rebate amount was subject to risk of error. An investor certainly could not intuit Mylan's critical omission, namely, that it rebated its most important product, the EpiPen, at only 13% of AMP, from its other disclosures in its Annual Report.

These omissions were misleading regardless of whether or not the agreements constituted antitrust violations actionable independent of Section 10(b).[8]

**3. Mylan Misled Investors About Its Price Fixing of Generic Drugs**

Defendants also repeatedly misled investors during the Class Period by describing in depth the competitive landscape Mylan faced, including the means by which Mylan competed, the "very competitive" drug industry in the U.S., and the "high[] sensitive[ity] of the U.S. drug marketplace to "price," yet omitting the crucial facts that Mylan competed through anticompetitive agreements to allocate the markets for, and to fix the price of, certain generic drugs.[9] (AC ¶¶ 104-200; *see, e.g.*, AC ¶¶ 225-26.) Defendants also misled investors during the Class Period by presenting income and revenue figures without disclosing that some of the income derived from Mylan's anticompetitive activity. *See, e.g.*, *In re Van Der Moolen*, 405 F. Supp. 2d at 407; *In re Marsh*, 501 F. Supp. 2d at 470; *In re LaBranche Sec. Litig.*, 405 F. Supp. 2d 333, 364-65 (S.D.N.Y. 2005).

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[8] In any event, Plaintiffs have indeed adequately pleaded that Mylan's anticompetitive agreements violated antitrust laws. Mylan's exclusive dealing agreements with schools violated Section 2 of the Sherman Act. (AC ¶ 102.) A firm violates Section 2 "when it acquires or maintains . . . a monopoly by engaging in exclusionary conduct" that has a net "anticompetitive effect." *United States v. Microsoft Corp*., 253 F.3d 34, 58 (D.C. Cir. 2001). The Amended Complaint alleges that Mylan's exclusive dealing agreements had anticompetitive effects, and does not allege any procompetitive effects, so a reasonable jury could find that these agreements had a net anticompetitive effect. (AC ¶ 102.) Contrary to Defendants' contention, Section 2 does not require a showing that the exclusive dealing agreements substantially foreclosed competition, *see Microsoft*, 253 F.3d at 71; *Dial Corp. v. News Corp*., 165 F. Supp. 3d 25, 36 (S.D.N.Y. 2016), and in any event, substantial foreclosure may reasonably be inferred here (AC ¶¶ 100-03).

The Amended Complaint likewise adequately pleads that Mylan's pay-for-delay agreement with Teva violated the Sherman Act. Under *FTC v. Actavis, Inc*., 133 S. Ct. 2223, 2238 (2013), a Plaintiff need merely allege "the presence of significant unjustified anticompetitive consequences" from a reverse payment to allege antitrust violation. Plaintiffs allege that Mylan participated in making a reverse payment to Teva to delay the introduction of Teva's generic product competitive with the EpiPen. The Amended Complaint supports the reasonable inference that the 2012 Settlement Agreement contained a reverse payment (AC ¶¶ 97-99), that this reverse payment was made based on Mylan's concerns about the strength of the EpiPen patents (AC ¶ 94), and that this reverse payment had significant unjustified anticompetitive effects (AC ¶ 100).

[9] *See, e.g.*, *In re Sotheby's Holdings, Inc. Sec. Litig*., 00 CIV. 1041 (DLC), 2000 U.S. Dist. LEXIS 12504, at *11, 13-14 (S.D.N.Y. August 30, 2000) (declining to dismiss a securities fraud claim where a corporation stated that competition with its competitor was "intense" when in fact the two corporations had entered into a price fixing agreement); *In re Par Pharm., Inc. Sec. Litig*., 733 F. Supp. 668, 678 (S.D.N.Y. 1990); *Menkes v. Stolt-Nielsen S.A.*, No. 3:03-CV-409(DJS), 2005 U.S. Dist. LEXIS 28208, at *24-25 (D. Conn. Nov. 10, 2005) (description of the pricing environment as "tight" and subject to continued "pressure" was actionable).

**a. Pleading an Independently Actionable Antitrust Violation Is Not Necessary To State a Section 10(b) Claim**

In response, Defendants again argue erroneously that Plaintiffs must plead an independently actionable antitrust violation in order to plead a Section 10(b) claim based on statements that touch on antitrust concerns. (Defs.' Mem. 6.) As stated above, this is not so.[10]

**b. Market Allocation of Doxycycline**

In any event, Plaintiffs have adequately pleaded market allocation and price fixing conspiracies. As Defendants recognize, Plaintiffs have pleaded that "Heritage and Mylan executives agreed to allocate the market for [doxycycline]," and have specified the exact date and means of the agreement, namely May 8, 2013, on a phone call between Heritage's President and CEO, Jeffrey Glazer and Mylan executives. (AC ¶¶ 116-17.) Defendants reject these allegations as conclusory (Defs.' Mem. 10), but they are anything but—as the Amended Complaint explains, the allegations are based on information obtained in a years-long antitrust investigation by forty-one states into drug companies including Mylan and Heritage, information detailed at length in a complaint filed by the attorneys general of those states against Mylan and Heritage, among other companies. (AC ¶ 113). Moreover, Heritage's former CEO and President, Jeffrey Glazer and Jason Malek, have pleaded guilty to felony charges for this conspiracy. (AC ¶¶ 199-200.) *See In re Propranolol Antitrust Litig.*, No. 16-cv-09901 (JSR), 2017 U.S. Dist. LEXIS 53390, at *22 (S.D.N.Y. Apr. 6, 2017) (holding allegations from the same states attorneys general complaint not conclusory).

[10] For example, in listing ways in which Mylan competes, yet omitting to disclose that Mylan competes in part through market allocation and price fixing agreements, Mylan misled investors to believe that Mylan was not engaged in this activity, when in fact it was. (*See, e.g.*, AC ¶¶ 225-26); *In re Sotheby's*, 2000 U.S. Dist. LEXIS 12504, at *13-14. This omission is misleading regardless of whether Mylan's market allocation and price fixing activity constitute independently actionable violations of antitrust law.

**c. Price Fixing of Other Generic Drugs**

Plaintiffs also have adequately pleaded a price fixing conspiracy relating to other generic drugs. (AC ¶¶ 104-11, 127-200.) In order adequately to allege a price fixing conspiracy based on conscious parallelism, "a plaintiff must show the existence of additional circumstances, often referred to as 'plus' factors, which, when viewed in conjunction with the parallel acts, [] serve to allow a fact-finder to infer a conspiracy."[11] *United States v. Apple, Inc.*, 791 F.3d 290, 315 (2d Cir. 2015). These plus factors traditionally include: "(1) a common motive to conspire; (2) evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators; and (3) evidence of a high level of interfirm communications." *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 781 (2d Cir. 2016).

The Amended Complaint contains detailed allegations of parallel price movements in five generic drugs marketed by Mylan during the Class Period, and contains similarly detailed allegations supporting the "plus factors" listed above. (AC ¶¶ 128-200). Indeed, Judge Rakoff in this District recently held that allegations substantially identical to those in the Amended Complaint are sufficient to allege that Mylan and others drug companies engaged in a conspiracy to fix the price of propranolol, one of the Price-Fixed Drugs.[12] *See In re Propranolol*, 2017 U.S. Dist. LEXIS 53390, at *13.

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[11] Moreover, "[p]arallel conduct alone may support an inference of conspiracy [when] it consists of complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernible reason." *Apple, Inc.*, 791 F.3d at 315.

[12] In particular, Judge Rakoff held that allegations concerning four plus factors, together with allegations of parallel price movements, were sufficient to plead an antitrust conspiracy, and the Amended Complaint alleges all of these factors. *First*, Judge Rakoff found that defendants "had a motive to increase prices because they operate in an oligopolistic market characterized by falling prices." *In re Propranolol*, 2017 U.S. Dist. LEXIS 53390, at *14-16. Here, as in *In re Propranolol*, the Amended Complaint alleges "market specific factors" leading to these falling prices, including that generic versions of the Price-Fixed Drugs offered by different drug companies are "interchangeable," causing pricing to "remain[] stable" "for years" "at their historic, near direct cost levels" "as is typical in a mature market" (AC ¶¶ 154, 174, 180), and that "reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing" (AC ¶ 184). *Second*, Judge Rakoff found that "the price increases were against defendants' self-interest because in a competitive market, defendants should have tried to undercut each other's prices to increase their market share," *id.* at *16-21, and the Amended Complaint alleges the same.

Defendants argue that Plaintiffs have not alleged direct evidence of a price fixing conspiracy (other than with respect to doxycycline) (Defs.' Mem. 10), but as explained above, Plaintiffs need not plead "direct evidence of conspiracy" as "conspiracies are rarely evidenced by explicit agreements but nearly always must be proven through inferences that may fairly be drawn from the behavior of the alleged conspirators." *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012). Defendants' other arguments fail even to address the legally relevant question, whether the Amended Complaint adequately pleads the traditional "plus factors." (Defs.' Mem. 10-12); *Gelboim*, 823 F.3d at 781; *In re Propranolol*, 2017 U.S. Dist. LEXIS 53390, at *13-24. While the fact that parallel price increases did follow industry conferences and the fact that the markets for the Price-Fixed Drugs were oligopolistic both support a finding of antitrust conspiracy, whether either fact on its own would be sufficient to plead antitrust conspiracy is not a question that even need be asked in the proper analysis of the traditional plus factors outlined above.[13] *Id.*

**B. Plaintiffs' Allegations Make Clear that Defendants Acted with Scienter**

The second element of Plaintiffs' Section 10(b) claim with which Defendants take issue is scienter. In the Second Circuit, a strong inference of scienter "can be established by alleging facts to show . . . strong circumstantial evidence of conscious misbehavior or recklessness."

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(AC ¶ 161.) *Third*, Judge Rakoff found that "defendants frequently communicated at trade association meetings," *id.* at *22, and the Amended Complaint likewise contains detailed allegations regarding regular communications between the drug cartel participants. (AC ¶¶ 175-79.) *Fourth*, as Judge Rakoff and the Amended Complaint have noted, there are ongoing state and federal investigations for price manipulation of generic drugs, including the Price-Fixed Drugs. *Id.* at *24.

[13] Defendants' argument that some of the generics markets, in Defendants' eyes, do not exhibit parallel price movements (Defs.' Mem. 11 n.8) is facially implausible given the clearly parallel price movements of each of the Price-Fixed Drugs as graphed in the Amended Complaint. Yet regardless, whether certain price increases constitute parallel movement is a highly factual question that is wholly inappropriate for resolution on a motion to dismiss. *See In re Platinum & Palladium Antitrust Litig.*, No. 1:14-cv-9391-GHW, 2017 U.S. Dist. LEXIS 46624, at *102 (S.D.N.Y. Mar. 28, 2017) ("The choice between two plausible inferences that may be drawn from [alleged price movements] is not a choice to be made by the court on a Rule 12(b)(6) motion.") (quoting *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012).) Moreover, Defendants do not dispute that the markets for albuterol sulfate and clomipramine exhibited parallel price movement during the Class Period, and Defendants' statements were misleading if Defendants engaged in price fixing with respect to *any* of the Price-Fixed Drugs.

*ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009); *Menaldi*, 164 F. Supp. 3d at 585. Conscious misbehavior encompasses, among other things, "deliberate illegal behavior," *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). Recklessness with respect to an omission is adequately pleaded where "the plaintiff has pleaded facts demonstrating that [the defendant] had access to information indicating that [the omission] was [misleading]." *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 456 (S.D.N.Y. 2005).

**1. Defendants Do Not Contest That They Had Access to Information about CMS's EpiPen Determination and the DOJ's Subpoena**

Defendants make no effort to dispute, as they cannot, that Defendants had access to information about CMS's determination and the DOJ's subpoena, and so concede scienter with respect to Mylan's CMS Determination Omissions and DOJ Subpoena Omissions. *See Menaldi*, 164 F. Supp. 3d at 584. These omissions survive Defendants' Motion without contest.

**2. Defendants Knew the EpiPen Was Misclassified**

There is no question that Defendants, at a minimum, knew facts and had access to information indicating that the EpiPen was misclassified, and as such, had access to information indicating that their EpiPen Misclassification Omissions and 13% Rebate Omissions (defined above in Part III(A)(1)) were misleading.

**a. CMS Expressly Informed Mylan the EpiPen Was Misclassified**

As explained above and in the Amended Complaint, CMS, the federal agency responsible for interpreting the MDRP legal regime and implementing the MDRP, expressly told Mylan prior to the start of the Class Period that the EpiPen was misclassified. (*See supra* Part III(A)(1); AC ¶ 65.) Defendants have no response to this dispositive fact; they mention it only in passing in discussing government investigations (Defs.' Mem. 16), but a determination by CMS of misclassification, communicated expressly to Mylan, is not a government investigation.

**b. Any Purported 1997 Letter to Dey Was Superseded by CMS Communications Before the Start of the Class Period**

Defendants argue instead that they could not have knowingly misclassified the EpiPen because according to them, CMS purportedly had sent a letter two decades ago to Mylan's predecessor Dey in 1997 stating that the EpiPen was properly classified. (Defs.' Mem. 3, 6-7.) As an initial matter, any argument by Defendants that relies on any such purported 1997 letter, or any excerpt thereof, should be disregarded entirely because there is no legitimate basis on which the Court may take judicial notice of, or otherwise rely on, such a purported letter or its contents for the purposes of this motion.[14]

Plaintiffs have located a letter online that appears to contain the language cited in Defendants' motion. *See* Ex. A to Declaration of Austin Van. Even if Exhibit A were the purported 1997 letter (Plaintiffs have no basis to make, and do not make, such an assumption), and even if Exhibit A were authentic and actually sent to Dey in 1997 (Plaintiffs dispute, prior to discovery, that any such letter is or was), Exhibit A contains reasons on its face to doubt that the letter represents an official determination by CMS as to EpiPen's proper classification.

[14] Defendants argue that the Court both should consider and assume the truth of the contents of a news article referenced in the Amended Complaint loss causation section because the Amended Complaint quotes a few lines from the news article, and so (Defendants claim) incorporates the article by reference, and because Plaintiffs allegedly relied on the article in the Amended Complaint. However, "[l]imited quotation does not constitute incorporation by reference." *Cosmas v. Hassett*, 886 F.2d 8, 13 (2d Cir. 1989); *Goldman v. Belden*, 754 F.2d 1059, 1066 (2d Cir. 1985). Likewise, though the news article and Mylan's 2016 8-K referenced by Defendants are in no way "integral" to the Amended Complaint (as for example, a contract in a breach-of-contract action might be), "even if a document is 'integral' to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document." *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006); *MBody Minimally Invasive Surgery, P.C. v. United HealthCare Ins. Co.*, 2016 U.S. Dist. LEXIS 108598, at *20-21 (S.D.N.Y. Aug. 15, 2016). Plaintiffs have no reason blindly to accept, and so dispute, the accuracy of the statements in the news article that CMS informed Mylan's predecessor two decades ago that the EpiPen could be classified as a generic drug.

Defendants also argue that the Court must accept as true everything stated in Mylan's 2016 8-K. (Defs.' Mem. at 3 n.2.) Even if Defendants were correct (they are not, for the reasons above), the 8-K merely states that Mylan has classified the EpiPen "based on longstanding written guidance from the federal government." That statement is consistent with Mylan's having disclosed merely that it (purportedly) had classified EpiPen based on CMS's general public guidance regarding classification; the statement makes no mention of any purported 1997 letter from CMS to Mylan. Viewing the facts in the "light most favorable to the plaintiff[s]," as the Court must on this motion, the 8-K in no way supports Mylan's self-serving claim that CMS informed its predecessor in 1997 that the EpiPen could be classified as a generic. *Courtenay Communs. Corp. v. Hall*, 334 F.3d 210, 213 (2d Cir. 2003); *In re ITT Educ. Servs.*, 34 F. Supp. 3d 298, 304 (S.D.N.Y. 2014) (Oetken, J.) (Court draws "all inferences in the plaintiff's favor").

*First*, Exhibit A comes from an individual whose title, "Senior Health Insurance Specialist," suggests that his role did not concern MDRP classifications. *Second*, the Exhibit purports to rely on the expertise of "Herb Gerstenzang, FDA," but his role is not specified, and the FDA does not have a role in interpreting the MDRP statute, so Powell's reliance on the FDA for the classification was in error. *Third*, the Exhibit offers "additional documentation," and so suggests on its face that more official documentation exists for such a determination.

Yet crucially, even if CMS had sent such a letter to Mylan's predecessor two decades ago (which Plaintiffs do not concede), even if the Court properly could consider it on this motion (the Court cannot), and even if Exhibit A were this purported letter and were reliable on its face (it is not), that guidance obviously would have been superseded by CMS's subsequent guidance communicated expressly to Mylan prior to the start of the Class Period that the EpiPen was misclassified. HHS IG informed CMS that the EpiPen was misclassified on March 16, 2009. (AC ¶ 65), and CMS informed Mylan of the misclassification shortly thereafter, and well before the start of the Class Period (*id.*), as Senator Grassley recently confirmed (*see* supra note 2).[15] Accordingly, Mylan knew the EpiPen was misclassified (or at a minimum, knew that EpiPen was virtually certain to be misclassified, which amounts to substantially the same proposition).

**c. Numerous Additional Allegations Make Clear that Defendants Knew the EpiPen Was Misclassified**

While CMS's having told Mylan expressly that the EpiPen was misclassified clearly is sufficient to establish that Defendants, at a minimum, "had access to information" indicating that

[15] Defendants also attempt to argue that they could not knowingly have misclassified the EpiPen because under Plaintiffs' straightforward understanding of the statute (which CMS and Mylan advanced for years), the term "original" in the phrase "original NDA" used in the definition of S and I drugs purportedly would have no meaning. (Defs.' Mem. 6-7.) Yet even if there were some question about the effect of the term "original" in the MDRP statute (which Plaintiffs do not concede), the role of addressing any such question would fall in the first instance on CMS, which administers the MDRP (AC ¶¶ 41, 42, 48), and as noted above, CMS expressly told Mylan prior to the start of the Class Period that the EpiPen was misclassified for the purposes of the MDRP.[15] (AC ¶ 65.) Notably, to Plaintiffs' knowledge, Defendants have not advanced, here or elsewhere, any argument for why EpiPen somehow was not marketed under an "original" NDA.

the EpiPen was misclassified, numerous additional allegations reinforce this conclusion. While Defendants repeatedly argue that certain allegations, standing alone, are not sufficient to demonstrate scienter (Defs.' Mem. 14-17), Defendants' argument flatly ignores the requirement from *Tellabs* that the Court must judge the sufficiency of scienter allegations "holistically" rather than "in isolation." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007).

***DOJ Subpoena***. In November 2014, the DOJ issued a subpoena to Mylan, which indicated that the DOJ believed Mylan to have misclassified the EpiPen. While the existence of an investigation may not independently be dispositive, "courts have considered a governmental investigation as one piece of the puzzle when taking a 'holistic' view of the purported facts as they relate to scienter." *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 380 (E.D.N.Y. 2013) (citing *In re Bristol Myers Squibb Co. Secs. Litig.*, 586 F. Supp. 2d 148, 168 (S.D.N.Y. 2008)); *Lipow v. Net 1 UEPS Techs., Inc.*, 131 F. Supp. 3d 144, 164 (S.D.N.Y. 2015) (cited by Defendants) ("the existence of an investigation . . . may be considered by the Court as part of its analysis"). Mylan's willingness to pay $465 million to settle the DOJ's investigation into the classification of the EpiPen likewise suggests Mylan recognized the classification to have been egregious. (AC ¶ 85.) Defendants are aware of no authority that suggests that the Court may not consider this settlement agreement in its holistic analysis.

***Core Operations***. At a minimum, the magnitude of Defendants' fraud and the fact that the fraud concerned Mylan's core operations "buttress the allegations of scienter." *In re Salix Pharm., Ltd.*, No. 14-CV-8925, 2016 U.S. Dist. LEXIS 54202, at *50 (S.D.N.Y. Apr. 22, 2016). Defendants do not dispute that the EpiPen was part of Mylan's core operations (indeed, sales of the EpiPen generated between 28% and 95% of Mylan's operating profits during the Class Period), and Mylan overcharged Medicaid by around one billion dollars or more. (*See* SOF; AC

¶¶ 33, 311.) Each of the Individual Defendants served as CEO, CFO or Chief Accounting Officer, all executive-level positions that guaranteed their knowledge of the EpiPen and the enormously consequential classification of the EpiPen under the MDRP.

***SOX Certifications***. Defendants' SOX certifications in Mylan's Annual Reports likewise support an inference of scienter in the Court's holistic analysis. *See, e.g.*, *In re Atlas Air Worldwide Holdings Inc. Secs. Litig.*, 324 F. Supp. 2d 474, 491 (S.D.N.Y. 2004). The Annual Reports, certified by Defendants, expressly stated that "[s]ales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate . . . 23% of the [AMP]."[16] (AC ¶ 329.)

***Corporate Scienter***. Plaintiffs have adequately pleaded corporate scienter with respect to Mylan's knowledge of the EpiPen misclassification. The knowledge of the Individual Defendants, as "management-level employees," may be "readily attributed" to Mylan. *In re Marsh*, 501 F. Supp. 2d at 481. Moreover, and in any event, all of Mylan's misstatements and omissions relating to the EpiPen in its SEC filings, at a minimum, "would have been approved by corporate officials sufficiently knowledgeable about" the legal classification of the EpiPen, CMS's determination, and the DOJ's subpoena, "to know that those statements were misleading." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015); *see In re Silvercorp Metals Sec. Litig.*, 26 F. Supp. 3d 266, 276-77 (S.D.N.Y. 2014). Accordingly, corporate scienter is properly alleged.

### 3. Defendants Knew About Mylan's Anticompetitive Conduct

Though not required to do so, Plaintiffs have pleaded adequately that Defendants violated antitrust laws through their use of exclusive dealing and pay-for-delay agreements, and by

[16] Plaintiffs do not deny, as Defendants seem to suggest (Defs.' Mem. 16), that Defendants "reasonably believed [this statement] to be true;" indeed, Defendants' knowledge of the correct rule for classifying drugs marketed under an NDA (such as the EpiPen) supports the inference that Defendants acted with scienter in omitting the fact that their most important drug, the EpiPen, was not correctly classified according to that rule.

engaging in an antitrust conspiracy to allocate the market for doxycycline and fix the prices of the Price-Fixed Drugs. (*See supra*, Part III(A)(2)-(3).) Even standing alone, these pleadings are sufficient to allege conscious misbehavior, and therewith scienter, with respect to this anticompetitive activity. *See Novak*, 216 F.3d at 308. Numerous additional allegations cement the conclusion that Defendants "knew facts or had access to information" regarding Mylan's anticompetitive activity. *In re Alstom*, 406 F. Supp. 2d at 456.

***Confidential Witness Statements***. A confidential witness ("CW") has made clear that each of the Individual Defendants participated in the pricing decisions, including market allocation and price fixing activity, at issue. (AC ¶¶ 110-11, 332-33.) CW attested that all material pricing decisions at Mylan "involved all of Mylan's top executives" and that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions. (AC ¶ 333.) These allegations support a strong inference that the Individual Defendants, as CEOs, CFOs, and top executives, were aware of and participated in the overnight, stratospheric "price adjustments" at issue in Plaintiffs' price fixing allegations.[17]

***Government Investigations***. The numerous investigations by the DOJ, SEC, Congress and attorneys general of forty states into Mylan's market allocation and price fixing conspiracies likewise support the inference that Defendants knew about or had access to information indicating the existence of these conspiracies. As noted above, the existence of investigations like these bolster the inference of scienter in the Court's holistic review of scienter allegations.

[17] Moreover, contrary to Defendants' assertion (Defs.' Mem. 18), CW is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by [CW] would possess the information alleged." *Novak*, 216 F.3d at 314; *see In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 203, 220 (S.D.N.Y. 2008). CW worked directly with Defendant Sheehan, and worked in positions that clearly concerned pricing and positioned CW to know about how pricing decisions at Mylan were made and whom they involved. (AC ¶¶ 110, 332.)

*In re Bristol Myers Squibb.*, 586 F. Supp. 2d at 168. Moreover, these investigations have uncovered direct evidence of Defendants' scienter.[18]

***Core Operations***. That Mylan's sales of generic drugs are part of its core operations (AC ¶ 26) "buttress the allegations of scienter." *In re Salix*, 2016 U.S. Dist. LEXIS 54202, at *50.

***SOX Certifications***. Defendants' SOX certifications likewise support an inference of scienter in the Court's holistic analysis. *See, e.g.*, *In re Atlas*, 324 F. Supp. 2d at 491.

***Corporate Scienter***. As above, the knowledge of the Individual Defendants may be "readily attributed" to Mylan, *In re Marsh*, 501 F. Supp. 2d at 481; *Loreley*, 797 F.3d at 177.

### C. Plaintiffs Have Adequately Pleaded Loss Causation for Each of the Dates Specified in the Amended Complaint

The third element of Plaintiffs' Section 10(b) claims, loss causation, "is not intended to impose a great burden on a plaintiff," as Plaintiffs need only meet Rule 8 notice pleading standards, which are met by "provid[ing] a defendant with some indication of the loss and the causal connection that the plaintiff has in mind . . . ." *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 404 (2d Cir. 2015) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005); *In re Bear Stearns Cos., Inc. Sec., Derivative, & ERISA Litig.*, 763 F. Supp. 2d 423, 488 (S.D.N.Y. 2011). "To plead loss causation, the complaint[] must allege facts that support an inference that [defendant's] misstatements and omissions concealed the circumstances that bear upon the loss suffered such that plaintiffs would have been spared all or an ascertainable portion of that loss absent the fraud." *In re Bear Stearns*, 763 F. Supp. 2d at 505. "Whether the truth comes out by way of a corrective disclosure describing the precise fraud

[18] For example, the investigation by the states attorneys general revealed that Mylan executives and Heritage executives Malek and Glazer expressly agreed to allocate the market for doxycycline. (AC ¶ 116-17.) Malek and Glazer have pleaded guilty to antitrust conspiracy, and as Judge Rakoff has found, "Malek and Glazer enacted their price fixing scheme contemporaneously with the alleged conspiracies and, by virtue of their high-level corporate positions, were plausibly responsible for setting prices of [Price-Fixed Drugs, including] Propranolol." *In re Propranolol*, 2017 U.S. Dist. LEXIS 53390, at *25.

inherent in the alleged misstatements, or through events constructively disclosing the fraud, does not alter the basic loss-causation calculus." *In re Vivendi*, 838 F.3d at 262.

Plaintiffs have provided indications "of the loss and the causal connection [Plaintiffs] ha[ve] in mind" in the Amended Complaint.[19,20] *Dura*, 544 U.S. at 347; (AC ¶¶ 298-324.)

***August 19-24, 2016.*** The Amended Complaint alleges that, through Defendants' anticompetitive activity relating to the EpiPen, including its use of pay-for-delay and exclusive dealing agreements, Mylan was able to increase the price of EpiPen by more than 400% during the Class Period, which led to public outcry and calls for antitrust investigations. (AC ¶¶ 17, 92, 100, 103.) But for Defendants' failure to disclose its anticompetitive activity, Mylan would not have been able to engage in that activity, and so could not have raised prices to supracompetitive levels and could not have created public outrage and invited calls for antitrust investigations.

***October 12, 2016.*** Likewise, in failing to disclose that they had misclassified the EpiPen, Defendants concealed the likelihood that Mylan would have to pay significant fines for the misclassification, and that risk materialized in part when Mylan agreed to pay $465 million to settle the DOJ's investigation, and in part when Evercore revealed on October 12, 2016 that that settlement might require Mylan to pay much more than $465 million. (AC ¶¶ 85, 311-14.)

***October 5 and 7, November 3 and 10, 2016 and January 10, 2017.*** Defendants argue that the corrective disclosures on these dates revealed no new information to the market (Defs.' Mem. 21), but the news articles cited for these dates clearly do reveal new and relevant facts.[21]

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[19] Defendants do not dispute that the disclosure on September 2, 2016 that CMS had found the EpiPen was misclassified revealed the truth omitted in the CMS Determination Omissions and partially revealed the truth omitted in DOJ Investigation Omissions, and so do not dispute that loss causation has been pleaded sufficiently with respect to these misstatements.

[20] Defendants argue that Plaintiffs have failed to plead loss causation relating to Mylan's exclusive dealing agreements with schools (Defs.' Mem. 8), but that argument ignores multiple disclosures encompassing Mylan's anticompetitive activity, including the disclosure on January 30, 2017 that the FTC was investigating Mylan for antitrust violations. (AC ¶¶ 323-24.)

## IV. ARGUMENT: PLAINTIFFS HAVE PROPERLY PLEADED VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT

As Plaintiffs have adequately pleaded primary violations of Section 10(b), Defendants' only argument for dismissal of Plaintiff's Section 20(a) claim fails. (Defs.' Mem. 22.)

## V. ARGUMENT: PLAINTIFFS HAVE PROPERLY PLEADED VIOLATION OF ISRAELI SECURITIES LAW

As Defendants recognize (Defs.' Mem. 22), the Israeli Investor Group's Israeli law claims are based on *Israeli Securities Law*—they are based on the incorporation into Israeli law of Sections 10(b) and Section 20(a) of the Exchange Act. (*See* Declaration of Amir Licht ("Licht Decl."), ¶¶ 6-8, 41-42, 51-65.) As Defendants have failed to provide any reason why Plaintiffs' U.S. law claims fail, Defendants likewise have failed to provide any reason why the Israeli law claims fail.

### A. Personal Jurisdiction

Defendants argue that the Court lacks personal jurisdiction over Defendants with respect to the Israeli law claim. (Defs.' Mem. 22-23.) To the contrary, the Court has specific (and even general)[22] personal jurisdiction over Mylan for this claim. This Court has specific personal

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[21] In particular, the Bloomberg News article published on October 5, 2016 disclosed a letter from CMS's Acting Director that had never before been made public, in which he provided new authority from a named source at CMS for the proposition that CMS had informed Mylan of the misclassification of the EpiPen, and revealed for the first time that CMS had "*expressly* told Mylan" "*on multiple occasions*" of the EpiPen misclassification. (AC ¶ 309 & n.55.) The letter also provided new information about the U.S. Government's massive expenditures on the EpiPen. (*Id.*) On October 7, 2016, Evercore released a new analysis showing that Mylan had overcharged Medicaid by over $707 million by misclassifying the EpiPen.[21] (AC ¶ 311.)

The November 3, 2016 Bloomberg News article revealed, among other things, that the scope of the DOJ's investigation into generic drug price fixing "spans more than a dozen companies and about two dozen drugs," facts that had not been disclosed previously in Mylan's 2016 10-K or elsewhere. (AC ¶ 315 & n.59.) The November 10, 2016 FiercePharma report revealed for the first time that Evercore had determined that Mylan could face liability between $380 million and $770 million under the DOJ's price collusion investigation. (AC ¶ 317.)

On January 10, 2016, The Philadelphia Inquirer revealed for the first time that Heritage executives Glazer and Malek had been convicted of participating in the price fixing conspiracy with Mylan, in effect confirming the existence of the conspiracy and confirming previous reports from unnamed sources that the men were intending to plead guilty. (AC ¶ 321 & n.62.)

[22] A District Court in New York has general personal jurisdiction over a defendant when the defendant has "continuous and systematic" contacts with New York. *See Int'l Diamond Imps., Inc. v. Med Art, Inc.*, No. 15-CV-4045, 2017 U.S. Dist. LEXIS 102257, at *4 (S.D.N.Y. June 29, 2017). As shown in the Amended Complaint and in

jurisdiction over a defendant if the defendant had "minimum contacts" with New York "relat[ing] to" the acts that form the subject matter of the litigation. *Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez*, 305 F.3d 120, 127 (2d Cir. 2002). Indeed, where the defendant "has substantial contacts with the forum (even if not sufficient to establish general jurisdiction), the court may accept a more attenuated relation between the defendant's contacts with the forum and the plaintiff's cause of action." *Ponte v. Universal City Dev. Partners, LTD.*, No. 07-CV-2360 (KMK) (LMS), 2008 U.S. Dist. LEXIS 3528, at *36-37 (S.D.N.Y. Jan. 15, 2008).

Mylan had far more than "minimum contacts" with New York relating to Plaintiffs' Israeli law claim. Mylan stock is routinely purchased on the TASE and sold on the NASDAQ in New York (through New York-based DTC) (Licht Decl. ¶ 49), so many of the losses suffered by the TASE Investor Class occurred in New York. Mylan made the numerous SEC disclosures at issue in the Israeli law claim in order to comply with NASDAQ listing requirements, and so purposefully directed these disclosures to New York, the global epicenter of financial analysis, where financial analysts digested the disclosures and precipitated trades that lowered Mylan's share price on both exchanges and caused the TASE Investor Class's losses. Moreover, Mylan marketed the EpiPen and the Price-Fixed Drugs nationwide during the Class Period, including in New York, and but for this marketing, Plaintiffs would not have suffered losses. (AC ¶¶ 26, 340.)

**B. Supplemental Jurisdiction**

Defendants also argue that the Court should decline to exercise supplemental jurisdiction over the Israeli Law claim. (Defs.' Mem. 23-24.) In any civil action in which a district court has original jurisdiction, it "shall" also, with limited exceptions, "have supplemental jurisdiction over

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SEC filings cited in the Amended Complaint, Mylan has such continuous and systematic contacts with New York. (*See, e.g.*, AC ¶ 27; 2016 10-K (Mylan has offices in New York; "The Company also leases warehousing, distribution and administrative facilities in . . . New York . . . .")

all other claims that are so related to the claims in the action within such original jurisdiction that they form part of the same case or controversy." 28 U.S.C. § 1367(a).

Defendants do not dispute, as they cannot, that the Israeli law claim forms part of the same "case or controversy" as the Exchange Act claims—the Israeli law and Exchange Act claims are substantially the same. Instead, Defendants point to a few decisions where courts have declined to exercise supplemental jurisdiction. Defendants' cases are clearly distinguishable—unlike in the cases cited by Defendants,[23] here Plaintiffs' Israeli law claims are identical in content and substantially identical in law to the U.S. law claims.[24]

**C. Forum Non Conveniens**

Finally, Defendants argue that the Israeli law claim should be dismissed under the doctrine of *forum non conveniens*. To determine what best serves "the convenience of the parties," the Court principally must balance the "private and public interests" at stake.[25] *See International Equity Inv., Inc. v. Cico*, 427 F. Supp. 2d 503, 504 (S.D.N.Y. 2006). "The private

[23] For example, in *Gordillo v. Bank of N.Y. Mellon Corp*., the court reasoned that "[g]iven that the parties are already litigating the validity of the purported settlement agreement in another jurisdiction, and that the evidence will be found in that jurisdiction and its law will apply, basic principles of judicial economy, comity, and convenience do not favor the resolution of this dispute in this forum. No. 12-cv-0212 (DF), 2014 U.S. Dist. LEXIS 96789, at *33 (S.D.N.Y. July 14, 2014). None of those factors applies here, where no litigation has progressed in another jurisdiction, the key evidence at issue is located in the U.S., and Sections 10(b) and 20(a) of U.S. law will apply (through Israeli law).

[24] Defendants also appear to argue that the claims at issue are beyond those recognized to be within the territorial reach of Section 10(b) of the Exchange Act under *Morrison v. Nat'l Austl. Bank Ltd*., 561 U.S. 247 (2010). (Defs.' Mem. 24.) Yet the holding in *Morrison*, which concerned only the territorial reach of U.S. law, *id*. at 247, 253-54, is wholly irrelevant to the court's decision to grant supplemental jurisdiction over an Israeli law claim. Israeli Securities Law has adopted the Exchange Act for dual-listed securities, and here, the Court would be applying Israeli law's adopted version of Sections 10(b) and 20(a) to the Israeli law claim, not U.S. law. The Israeli Supreme Court has determined that for dual-listed securities, *Morrison* does not apply to Israeli law's adopted versions of Sections 10(b) and 20(a). (*See* Licht Decl. ¶¶ 57-58.) That is, the Israeli Supreme Court has determined that even if the U.S. Congress did not intend to grant a Section 10(b) cause of action to Israeli TASE traders for trades of dual-listed securities of a non-U.S. corporation, the Israeli Knesset did intend to grant such a cause of action. (*See* Licht Decl. ¶ 58.)

[25] Contrary to Defendants' suggestion (Defs.' Mem. 25), Plaintiffs' choice of forum is entitled to some degree of deference. "[T]he greater the plaintiff's or the lawsuit's bona fide connection to the United States and to the forum of choice and the more it appears that considerations of convenience favor the conduct of the lawsuit in the United States, the more difficult it will be for the defendant to gain dismissal for *forum non conveniens*." *Iragorri v. United Techs. Corp*., 274 F.3d 65, 71-72 (2d Cir. 2001). This lawsuit's bona fide connection to the United States is indisputable, and considerations of convenience clearly favor the U.S. as the appropriate forum.

interest factors turn on which forum more conveniently can dispose of the litigation." *Id*. at 506. "[P]ublic interest factors tend to balance out in plaintiffs' favor" where "litigation, to which th[e] case is intimately related, will be resolved in [Plaintiff's selected] Court in any event." *Id*.

Here, there is no doubt that this Court can more conveniently dispose of the litigation than an Israeli court. All significant witnesses and evidence are located in the U.S. where Mylan is headquartered, and the substantive content of only U.S. securities law will be applied. Moreover, as Israeli Securities Law subordinates itself to U.S. law for dual-listed securities, the Israeli courts likely will stay the Israeli Actions pending the outcome of this litigation. (Licht Decl. ¶¶ 66-69.) To require the TASE Investor Class to wait until these proceedings have been resolved before beginning proceedings in Israel would impose a significant "inconvenience" on these investors.

Defendants' argument that they face the prospect of double exposure if the Israeli law claims are litigated in the U.S. is based on a misstatement of Israeli law. (Defs.' Mem. 24-25.) As explained in the Declaration of Amir Licht (a drafter of the Israeli dual-listing law at issue) (Licht Decl. ¶¶ 70-83), there is no serious dispute that Israel would accept and enforce a U.S. judgment in a securities class action.[26]

## VI. CONCLUSION

For all the above reasons, Defendants' Motion should be denied in its entirety.

[26] Defendants' Israeli law advocate, Zvi Agmon, bases his opinion to the contrary (Decl. Zvi Agmon ¶¶ 15-17.) on a patent misstatement of the Israeli Supreme Court's holding in *Stern v. Verifone Holdings, Inc.*, CA 3973/10 [2015] IsrSC (Ex. 8 to Atkinson Decl.). Agmon notes that the Israeli Supreme Court has held that the U.S. court must have a "real and substantial" connection to the Israeli law claim, and then suggests that by this, the Israeli Supreme Court required that the U.S. court have a "greater" connection to the Israeli law claim than the Israeli court. This is a patent non sequitur: the requirement of a "greater" connection does not follow from the requirement of a "real and substantial connection." As Licht articulates (Licht Decl. ¶¶ 76-83), there is no serious dispute that this U.S. Court has a "real and substantial" connection to the Israeli law claim. That claim is based almost entirely on conduct that occurred in the U.S., all salient witnesses and evidence are located in the U.S., and the law to be applied is based on U.S. law.

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Respectfully submitted,

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